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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/063,477	04/20/1998	ROBERT A. HOLTON	FSU-10302	4505

321 7590 08/21/2006

SENNIGER POWERS  
ONE METROPOLITAN SQUARE  
16TH FLOOR  
ST LOUIS, MO 63102

EXAMINER
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DESAI, RITA J

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 08/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/063,477

Applicant(s)

HOLTON ET AL.

Examiner

Rita J. Desai

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 June 2006.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-23 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7/11/2006.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Claims 1-19 were pending.

New Claims 20-23 have been added.

The rejection of claims 1-19 (now 1-23 ) under 35 USC 112 first para still stands.

Applicants argue that the substituents are not a point of novelty. This is not convincing. If it is in the claims, to be allowable it should be a novelty. Applicants argue that it does not take part in the reaction hence it is not a point of novelty is neither convincing nor correct. It is very well known that large groups such a heteroaryls , heteroaromatic hydrocarbyls, large protecting groups , functional groups increasing the solubility's of the taxane derivatives , would have some reaction or interaction in the process. The basis of using protecting groups is made on this assumption that having a certain type of a group in a certain position would prevention a reaction to occur at that location. So the type and size of the groups and substitutions are critical to all process claims.

To satisfy the Written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that applicant were in possession of the claimed invention. Applicant's claims are drawn to a process of making taxane derivatives wherein the X2, X3, X4-X14 and Z9 have hydrocarbyl substituted hydrocarbyl, hetero aryl groups as substitutions. The specification on pages 6 and 7 have the recitation of the hydrocarbyl and heteroaryl. There is no definition given to these groups. The specification gives no guidance to one of ordinary skill in the art which groups are encompassed by this definition. The next one is protective group. The specification again does not define the groups in this category. The generic groups includes plethora of compounds, which has this functional moieties.

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The expression “hydrocarbyl, hetero aromatic , protective group” without i.e. partial or complete definition does not convey to one of ordinary skill in the art that applicants were in possession of the claimed subject matter. The functional language recited without any correlation does not meet the written description requirement for the expression “hydrocarbyl, hetero aromatic , protective group “ as one of ordinary skill in the art could not recognize or understand the structure from the mere recitation of the function. So the claims employing functional language at the point of novelty, such as applicants’ “claims “, neither provide those elements required to practice the inventions, nor “inform the public” during the life of the patent of the limits of the monopoly asserted. The expression could encompass a myriad of compounds and applicants claimed expression represents only an invitation to experiment regarding possible compounds.

Applicants claim 1 is also drawn to taxane which are limited compounds with no hetero aryl groups on it.

For the reasons given above the rejection still stands.

The rejection of claims 1-23 under 35 USC 103 over Sisti US 5750736 has been withdrawn as the prior art does not use any Lewis acid in its reaction.

### ***Conclusion***

Claims 1-23 still stand rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Rita J. Desai  
Primary Examiner  
Art Unit 1625

R.D.  
August 18, 2006

*RJ Desai*  
8/18/06